

Nos. 2014-1373, -1399

**United States Court of Appeals
for the Federal Circuit**

KANEKA CORPORATION, A JAPANESE CORPORATION,
Plaintiff-Appellant,

v.

**XIAMEN KINGDOMWAY GROUP COMPANY, A CHINESE
CORPORATION, PACIFIC RAINBOW INTERNATIONAL, INC., A
CALIFORNIA CORPORATION AND SHENZHOU BIOLOGY AND
TECHNOLOGY CO., LTD., A CHINESE CORPORATION,**
Defendants-Appellees.

Appeals from the United States District Court for the Central District of California
in No. 2:11-cv-02389-MRP-SS, Senior Judge Mariana R. Pfaelzer

**APPELLEE SHENZHOU BIOLOGY AND TECHNOLOGY CO., LTD.'S
PRINCIPAL BRIEF**

[NON-CONFIDENTIAL VERSION]

<p>TIMOTHY P. WALKER L. HOWARD CHEN HAROLD H. DAVIS, JR. JAS DHILLON K&L GATES LLP Four Embarcadero Center, Suite 1200 San Francisco, CA 94111 Telephone: (415) 882-8200 Facsimile: (415) 882-8220</p>	<p>MATTHEW B. O'HANLON K&L GATES LLP 10100 Santa Monica Boulevard 7th Floor Los Angeles, California 90067 Telephone: (310) 552-5000 Facsimile: (310) 552-5001</p>
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Attorneys for Defendant-Appellee

Shenzhou Biology and Technology Co., Ltd.

August 6, 2014

CERTIFICATE OF INTEREST

Counsel for Defendant-Appellee Shenzhou Biology and Technology Co., Ltd. (“Shenzhou”) certifies the following:

1. The full name of every party or amicus represented by us is: Shenzhou Biology and Technology Co., Ltd.
2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us is: Not applicable
3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by us are:

Shenzhou Tianchen Science and Technology Industrial Co., Ltd.
4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are: Timothy P. Walker, Howard Chen, Harold H. Davis, Jr., Jas Dhillon, and Matthew B. O'Hanlon (K&L Gates LLP).

Dated: August 6, 2014

By: /s/ Timothy P. Walker
Timothy P. Walker

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CONFIDENTIAL MATERIAL OMITTED

The material omitted on page 2 contains confidential business information concerning Shenzhou's process for making coenzyme Q₁₀ ("CoQ₁₀"); the material omitted from page 8 summarizes an International Search Report by a Japanese patent examiner which Kaneka designated as confidential pursuant to the parties' protective order; the material omitted from the bottom of page 9 summarizes notes of a meeting between Kaneka representatives and the Patent Examiner which Kaneka designated as confidential pursuant to the parties' protective order; the material omitted from page 14 contains test results designated as confidential pursuant to the parties' protective order; the material omitted on pages 15 and 16 contains confidential business information concerning Shenzhou's process for making CoQ₁₀; the material omitted from page 19 contains test results designated as confidential pursuant to the parties' protective order; the material omitted on page 21 contains confidential business information concerning Shenzhou's process for making CoQ₁₀; the material omitted from pages 45 and 46 summarizes notes of a meeting between Kaneka representatives and the Patent Examiner which Kaneka designated as confidential pursuant to the parties' protective order; the material omitted from pages 53 and 54 contains test results designated as confidential pursuant to the parties' protective order; the material omitted from page 57 contains test results designated as confidential pursuant to the parties'

protective order; the material omitted on pages 59 through 65 contains confidential business information concerning Shenzhou's process for making CoQ₁₀.

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STATEMENT OF RELATED CASES

Pursuant to Federal Circuit Rule 47.5, counsel for Shenzhou certifies the following:

1. No other appeal in or from the underlying civil action was previously before this Court or any other appellate court.
2. The case of *Zhejiang Medicine Co. Ltd. and ZMC-USA LLC v. Kaneka Corporation*, United States District Court for the Southern District of Texas, Houston Division, Case No. 4:11-CV-1052 (VDG), may be directly affected by this Court's decision.

Dated: August 6, 2014

By: /s/ Timothy P. Walker
Timothy P. Walker

JURISDICTIONAL STATEMENT

Shenzhou does not dispute jurisdiction.

I. STATEMENT OF THE ISSUES

1. Can the District Court's summary judgment of non-infringement be affirmed on the grounds that Appellant Kaneka Corporation ("Kaneka") waived the challenge by failing to explain how a change in the claim constructions would affect the summary judgment ruling?
2. Did the District Court correctly construe independent claims 1 and 11, which require extracting under an "inert gas atmosphere," to preclude an atmosphere that oxidizes reduced coenzyme Q₁₀ ("CoQ₁₀")?
3. Did the District Court correctly construe independent claims 22 and 33, which require extracting in a "sealed tank," to preclude an extraction tank with an open exhaust leading to another piece of equipment with a distinct function (solvent condenser)?
4. Did the District Court correctly construe independent claims 1 and 22, which provide "oxidizing thus-obtained reduced coenzyme Q₁₀ to oxidized coenzyme Q₁₀ and then extracting the oxidized coenzyme Q₁₀," to require oxidizing substantially all the reduced CoQ₁₀ before the extracting step?
5. Did the District Court correctly construe independent claims 11 and 33, which provide "extracting the reduced coenzyme Q₁₀ . . . and oxidizing the extracted reduced coenzyme Q₁₀," to require extracting the reduced

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CoQ₁₀ before any substantial oxidizing of the reduced CoQ₁₀?

6. If the case is remanded, did the District Court correctly require the use of the patent's disclosed "standardized" assay to determine the mole % of reduced CoQ₁₀ after culturing and before any other steps, where the evidence demonstrated that [REDACTED]

[REDACTED]

[REDACTED]?

7. Is Shenzhou entitled to summary judgment of non-infringement under the correct constructions of the disputed claim terms, where undisputed evidence showed:

a. [REDACTED]

[REDACTED];

b. [REDACTED]

[REDACTED];

c. [REDACTED]

[REDACTED];

d. [REDACTED]

[REDACTED]; and

e. [REDACTED]

[REDACTED]?

II. STATEMENT OF THE CASE

The District Court proceedings followed Kaneka's parallel unsuccessful infringement allegations regarding Shenzhou's process at the International Trade Commission ("ITC"). After full discovery, a hearing on the merits, and Commission review, the ITC found no infringement by any ITC respondent, including Shenzhou. Final Determination (A13422-436) *affirming* Initial Determination (A5296-5686) by Administrative Law Judge ("ALJ") Robert K. Rogers, Jr. Kaneka chose not to appeal the ITC Final Determination. On February 7, 2013, upon expiration of the appeals period, the District Court lifted the stay in the action below.

Though not binding on the District Court or this Court, the ITC investigation is relevant to this appeal because it concerned the same parties, the same patent, and the same accused process, and it included discovery proceedings and hearing evidence used as a source for evidence relied upon by the District Court. In addition, the District Court found the claim constructions of "inert gas atmosphere" and "sealed tank" by ITC ALJ Rogers to be substantively persuasive, though it adopted other claim constructions for the "oxidizing" and "culturing" claim limitations at issue on this appeal. (A3571-87).

During the ITC investigation, Kaneka asked for and received from Shenzhou operational documents describing the accused Shenzhou process, visited the

Shenzhou manufacturing facility to inspect the equipment used and take samples of intermediate and final process materials, analyzed the samples taken from Shenzhou, and deposed Shenzhou's designated corporate representatives respecting the accused process. Specific evidence from the ITC investigation relied upon by the District Court is included in the record and discussed *infra* where relevant. At the ITC hearing, there was no outstanding complaint about the completeness of Shenzhou's discovery responses.

In its brief, Kaneka refers to claim construction proceedings in a declaratory judgment case brought by Zhejiang Medicine Co. Ltd. ("ZMC") against Kaneka in the Southern District of Texas (called "the Texas Litigation" in Kaneka's Brief ("Kaneka Br.") at 14). Shenzhou has never appeared in the Texas Litigation.

III. STATEMENT OF THE FACTS

A. Commercial Microbial Production of Oxidized Coenzyme Q₁₀ From Reduced Coenzyme Q₁₀ Is Old in the Art

As admitted by Kaneka (Kaneka Br. at 8), the commercial manufacture of oxidized CoQ₁₀ is decades old. The basic steps of the '340 patent's claimed methods for using microorganisms to make oxidized CoQ₁₀ from reduced CoQ₁₀ were already known in the art: culturing cells, disrupting the cells, extracting, and oxidizing.

Coenzyme Q₁₀ was discovered in the 1950s (*see* A14345, 1:16-33) and was

the subject of extensive studies, particularly at Merck. Some of the work at Merck is summarized in U.S. Patent No. 3,066,080 (“*Folkers*” or “the Merck patent”), which issued in 1962 (A14345-50). The process described in *Folkers* (A14345-14350) for producing oxidized CoQ₁₀¹ included the steps of culturing (fermenting) CoQ₁₀-producing microorganisms (A14345-14350, col. 1:55-4:3), disrupting the cells (A14345-14350, col.3:29-52, 8:70-9:3), and extracting CoQ₁₀ from the microorganism cells using organic solvents (A14345-14350, col. 3:29-66, 9:3-6).

The ‘340 patent acknowledges that the following was also already known in the art of producing oxidized CoQ₁₀:

- The oxidized and reduced forms of CoQ₁₀ co-exist in living cells in an equilibrium between the oxidized and reduced forms of CoQ₁₀. (A67, col.2:24-27).
- Microbial cells produce a mixture of oxidized and reduced CoQ₁₀ having as much as 60 mole % reduced. (A67, col.2:38-44; 2:50-55).
- A mixture of oxidized and reduced CoQ₁₀ can be converted into oxidized CoQ₁₀ by oxidation. (A67, col.2:62-65).
- Reduced CoQ₁₀ is described in the prior art as an intermediate

¹ Folkers uses the bare term “coenzyme Q₁₀.” However, due to the conditions described, the final product is indisputably oxidized coenzyme Q₁₀. (A14345-14350)

substance in producing oxidized CoQ₁₀. (A67, col.2:65-67).

- Ambient air is able to oxidize reduced CoQ₁₀. (See A71, col.10:60-66 (“On the industrial production scale, complete oxygen elimination is very difficult to be achieved and, furthermore, fairly long periods of time are required for individual operation, unlike laboratory scale production, so that residual oxygen exerts a great adverse effect. The oxidation in question is directly connected to a subgeneration of oxidized coenzyme Q₁₀ from reduced coenzyme Q₁₀.”)).

The ‘340 patent specification erroneously asserts discovery of microorganisms able to produce reduced CoQ₁₀ at ratios higher than the 60 mole % acknowledged in the prior art. (See A68, col.3:16-17.) Contrary to the inventors’ assertion, patent examiners found that microbial production of reduced CoQ₁₀ at 70 mole % or higher during culturing is inherently disclosed in the prior art. (A12786-12802). Specifically, the examiners found that certain of the ‘340 patent’s example microorganisms were disclosed to be cultured in the claimed way in prior art references called Kondo and Yoshida, inherently yielding the same “high” ratio of reduced CoQ₁₀. (A12786-12802).

B. ‘340 Patent Prosecution History

U.S. Patent No. 7,910,340 (“the ‘340 patent”) is titled “Processes for Producing Coenzyme Q₁₀.” (A64-81). The ‘340 patent claims priority from

Japanese Patent Application 2001-398545, filed December 27, 2001. A Patent Cooperation Treaty (“PCT”) application was filed in Japan as International Application No. PCT/JP/13766 on December 27, 2002, which became the effective U.S. filing date upon entry into the U.S. national stage as Application No. 10/500,249 (the “first U.S. application”). (A12465-12912). A divisional application was filed as Application No. 11/981,181 on October 31, 2007 (the “divisional U.S. application”) (A12913-13284). Following further examination and amendment, the divisional U.S. application matured into the ’340 patent on March 22, 2011. (*See generally* A12913-13284; A64-81).

The principal disclosure of both applications and the claims elected during prosecution of the first U.S. application were directed to processes for producing *reduced* CoQ₁₀. (A12465-12912). In the divisional U.S. application Kaneka elected claims to processes for producing *oxidized* CoQ₁₀. (A12913-13284).

Initially, Kaneka sought to claim processes whose novelty was premised on the fermentation of microorganisms producing “microbial cells containing reduced coenzyme Q₁₀ at a ratio of not less than 70 mole % among the entire coenzymes Q₁₀” (the “70 mole % reduced limitation”).² (A12465-12912).

² A “mole” is a standard number of molecules, like a “dozen” or a “gross,” though instead of 12 or 144, a mole is Avogadro’s number, about 6.02×10^{23} , of molecules. Thus, the 70 mole % reduced coenzyme Q₁₀ limitation is a limitation

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However, as early as the International Search Report of the PCT Application, dated April 15, 2003, a Japanese Examiner pointed out that [REDACTED]

[REDACTED]. (See A12272-12275; *see also* A12465-12912).

Although Kaneka proposed other process claim limitations in addition to the 70 mole % reduced limitation—including disruption, extraction, and oxidation steps—during prosecution of the first U.S. application, the examiner rejected all of the claims as anticipated by and/or obvious based on Kondo and Yoshida, alone or in combination with another reference. (A12786-12802).

Kaneka ultimately abandoned the first U.S. application for producing reduced CoQ₁₀, and prosecuted instead the divisional U.S. application seeking claims for producing oxidized CoQ₁₀. Again, however, the examiner rejected the claims based on Kondo and Yoshida. (A13181-13205).

Kaneka then requested an interview with the Patent Examiner. In addition to counsel, Hirofumi Yamada and Reiko Mizutani attended the interview on behalf of Kaneka. (A13206-13208). At the ITC, Kaneka produced copies of notes from the

on the ratio of the number of reduced coenzyme Q₁₀ molecules to the number of molecules of all types of coenzyme Q₁₀.

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meeting. (A8817-23). [REDACTED]

[REDACTED]

[REDACTED]. (A8817-23).

Following the interview, Kaneka filed an amendment, cancelling all of the prior claims and substituting new claims that became the claims of the '340 patent. (A13209-13234). To avoid the Kondo and Yoshida references, these claims differed from the prior claims in the following ways:

- (1) all claims were amended to recite that the claimed process was to produce oxidized CoQ₁₀ "on an industrial scale"; and
- (2) "extracting" was to be conducted either "under an inert gas atmosphere" (independent claims 1 and 11) or "in a sealed tank" (independent claims 22 and 33). (A13209-13234).

C. The '340 Patent Claims Producing Oxidized Coenzyme Q₁₀ from at Least 70 Mole % Reduced Coenzyme Q₁₀

As acknowledged by Kaneka (Kaneka Br. at 9), the specification of the '340 patent is largely directed to producing reduced CoQ₁₀. (A64-81). The '340 patent's disclosure of producing oxidized CoQ₁₀ is limited to noting that—as already known in the art—reduced CoQ₁₀, once obtained, can be oxidized. (A68, col.3:43-46 ("oxidizing the reduced coenzyme Q₁₀ obtained from the microbial cells as an intermediate substance in producing oxidized coenzyme Q₁₀.")); *see also*

A67, col.17:1-29).

Tracking the specification's disclosed methods for producing reduced CoQ₁₀ and subsequently oxidizing it, Kaneka drafted claims to methods of producing oxidized CoQ₁₀ "on an industrial scale" that start with producing at least 70 mole % reduced CoQ₁₀. (A64-81). The '340 patent issued with four independent claims that include, in various combinations and order, the following steps (A64-81):

- culturing microorganisms that produce at least 70 mole % reduced CoQ₁₀ (independent claims 1, 11, 22, 33);
- disrupting the cells (claims 1, 22);
- oxidizing before extraction "thus-obtained reduced coenzyme Q₁₀" (claims 1, 22);
- oxidizing after extraction "the extracted reduced coenzyme Q₁₀" (claims 11, 33); and
- extracting either "the oxidized" (claims 1, 22) or "the reduced" (claims 11, 33) coenzyme Q₁₀, depending on whether oxidizing is before or after extracting.

The following chart diagrams the claim language of all four independent

claims:³

Independent Claims

Claim 1	Claim 11	Claim 22	Claim 33
<p>A process for producing on an industrial scale the oxidized coenzyme Q10 represented by the following formula:</p> <div style="text-align: center;"> </div>			
which comprises			
culturing reduced coenzyme Q10-producing microorganisms			
in a culture medium containing a carbon source, a nitrogen source, a phosphorus source and a micronutrient			
to obtain microbial cells containing reduced coenzyme Q10 at a ratio of not less than 70 mole % among the entire coenzymes Q10			
disrupting the microbial cells to obtain reduced coenzyme Q10; and		disrupting the microbial cells to obtain reduced coenzyme Q10; and	
oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10	extracting the reduced coenzyme Q10 by an organic solvent	oxidizing thus-obtained reduced coenzyme Q10 to oxidized coenzyme Q10.	extracting the reduced coenzyme Q10 by an organic solvent
and then extracting the oxidized coenzyme Q10 by an organic solvent	under an inert gas atmosphere, and	and then extracting the oxidized coenzyme Q10 by an organic solvent	in a sealed tank, and
under an inert gas atmosphere.	oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10.	in a sealed tank.	oxidizing the extracted reduced coenzyme Q10 to oxidized coenzyme Q10.

D. The Specification Only Describes Using an Inert Gas Atmosphere to Protect Reduced Coenzyme Q₁₀ from Oxidation

All of the ‘340 patent specification’s references to an “inert gas” relate to an atmosphere of gases that protect reduced CoQ₁₀ from oxidation. (A64-81).

Nowhere does the '340 patent specification use the term "inert gas" in relation to

³ Kaneka's brief does not quote the entire language of the independent claims. *See, e.g., Kaneka Br.* at 11.

safety precautions. (A64-81).

The '340 patent specification defines an "atmosphere of inert gas" as an example of a condition that protects reduced CoQ₁₀ from an oxidation reaction. (A74, col. 16:35-39 ("As '*the condition that reduced coenzyme Q₁₀ is protected from an oxidation reaction*' means, for example, a deoxygenized atmosphere (an ***atmosphere of inert gas*** such as nitrogen gas, carbon dioxide gas, helium gas, argon gas, or *hydrogen gas*, reduced pressure, a boiling condition . . .")))) (emphasis added).

The specification's definition of "atmosphere of inert gas" includes as an example hydrogen gas. *Id.* Though dangerously flammable, hydrogen gas is nevertheless characterized by the patent as "inert" because it will not oxidize reduced CoQ₁₀. (A74, col. 16:35-39)

The '340 patent specification notes that where oxidized CoQ₁₀ is being recovered, it is not necessary to protect reduced CoQ₁₀ from oxidation. (A75, col. 17:21-26) ("Incidentally, it is *not necessary* to carry out the *recovery of oxidized coenzyme Q₁₀ under 'the condition that reduced coenzyme Q₁₀ is protected from an oxidation reaction*', which is recommended for the recovery of reduced coenzyme Q₁₀, and the recovery may be carried out in consideration of general safe operation and the like.") (emphasis added).

Though not necessary, the '340 patent specification does not preclude the

use of an inert gas atmosphere to recover oxidized CoQ₁₀.

E. The Specification Does Not Use the Term “Sealed Tank” and Does Not Illustrate a “Sealed Tank”

The term “sealed tank” does not appear in the ‘340 patent specification or original claims. (A64-81).

The ‘340 patent has a single figure, described as a “countercurrent 3-step *continuous* extraction apparatus shown in FIG.1.” (A75, col.17:33-34 and A78, col.23:24-25) (emphasis added).

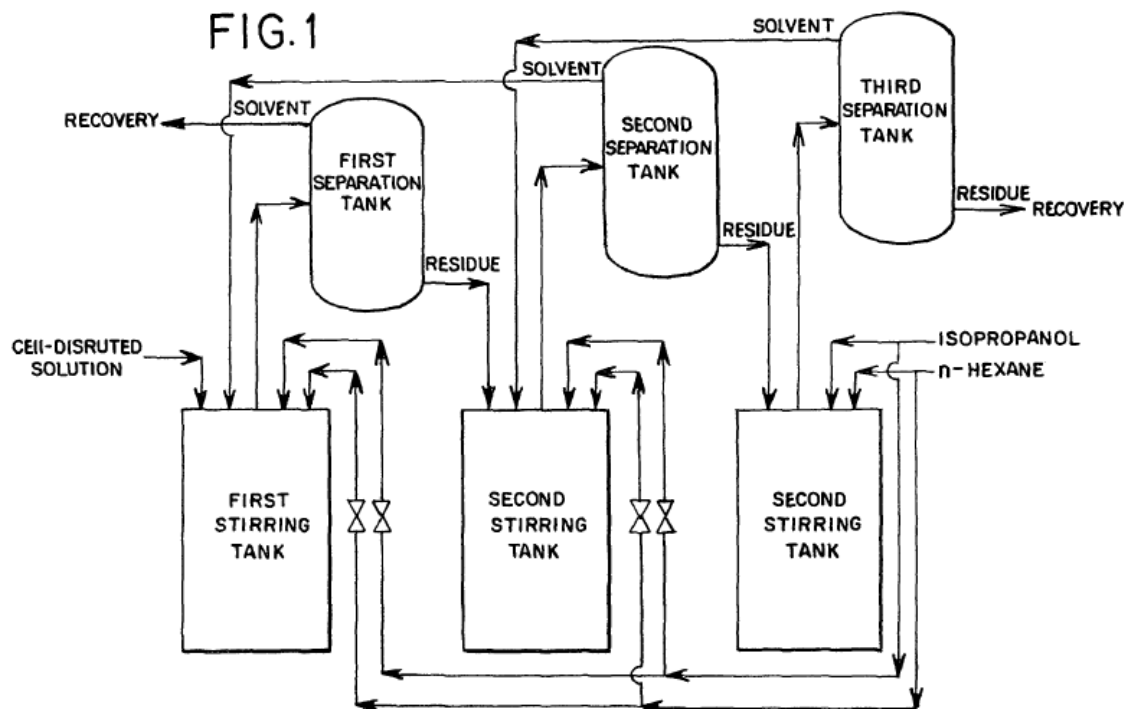


Figure 1 includes multiple features labeled “tank,” but none are labeled “sealed tank,” and all of the “tanks” have arrowed lines connecting them to other features of the diagram, which appear to indicate open channels.

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**F. The Specification Discloses “Standard” Methods for Culturing
and Assaying the Mole % Reduced Coenzyme Q₁₀**

As already noted, it is well known that oxidized and reduced CoQ₁₀ exist in an equilibrium in living cells and that reduced CoQ₁₀ can be oxidized by exposure to ambient air. (A67, col. 2:24-27; A6154-55). At the ITC, it was shown decisively that [REDACTED]

[REDACTED]. (A13650-13798; A6039:13-6042:10, 6043:16-6045:15, 6046:14-6051:25, 6057:11-6060:22, 6061:17-19, 6079:11-6082:8; A6109-6125 at Q. 206-235; A6138 at Q. 115, 6141-42 at Q.162, 6150-6164 at Q. 262-276, and 6158-59 at Q. 416-417; A6313-16 at Q. 174-194; A6331-6336).

Apparently anticipating these difficulties in determining the ratio of reduced CoQ₁₀ to all coenzymes Q₁₀, the ‘340 patent specification describes both a “standard” cell culturing process, and a “standard” assay procedure for determining the mole % of reduced CoQ₁₀ produced by a microorganism. (A68-71, col. 3:33-38, 4:40-50, 4:59-65, 7:55-8:18, 8:29-9:5). The specification states: “The above-mentioned measurement method is provided for the obtained result to reflect the reduced coenzyme Q₁₀ content and the ratio of reduced coenzyme Q₁₀ among the entire coenzymes Q₁₀ *as accurate as possible*, and *to standardize the content and the ratio of reduced coenzyme Q₁₀*, which can be guaranteed at the minimum.”

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(A69, col.5:36-42) (emphasis added).

These “standard” procedures were used by the inventors to screen microorganisms to be identified as “reduced coenzyme Q₁₀-producing microorganisms” in Tables 1, 2, and 3 of the ‘340 patent. (A75-77.)

G. The Accused Shenzhou Process

Because Shenzhou is making [REDACTED]
[REDACTED]. (A5775; A6659 at Table 6; A6097 at Table 3; A5972-6036). Accordingly, Shenzhou’s process does not include [REDACTED]
[REDACTED]. (A5775; A6659 at Table 6; A6097 at Table 3; A5972-6036). The undisputed evidence shows that the [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. (A5221-22; A5775; A5972-6036).

The material undisputed facts are as follows:

- [REDACTED]
[REDACTED]
[REDACTED] (A6097,

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Table 3; A6856, Table 3).⁴

- [REDACTED]
[REDACTED]. (A
5752-53; A6023-6024.) [REDACTED]
[REDACTED].
- According to Kaneka's own analysis, [REDACTED]
[REDACTED]. (A6097,
Table 3; A6856, Table 3).
- [REDACTED]
[REDACTED]. (A5755-56).

IV. SUMMARY OF ARGUMENT

Appellee Shenzhou seeks affirmance of the District Court's summary judgment of non-infringement. Appellant Kaneka alleges that Shenzhou and others⁵ use a process that infringes certain method claims of U.S. Patent No.

⁴ Evidence at the ITC hearing showed that [REDACTED]
[REDACTED], (A6097, Table 3; A6856, Table 3), [REDACTED].

⁵ Co-appellee Xiamen Kingdomway Group Company ("XKGC") is also alleged to manufacture coenzyme Q₁₀ using an infringing process.

7,190,340 (“the ‘340 patent”) to make oxidized CoQ₁₀ that is imported into and sold in the United States.⁶ (Kaneka Br. at 4-8).

A threshold issue is that Kaneka’s opening brief utterly fails even to address the propriety of the summary judgment order, not even including it among the issues on appeal. (*See* Kaneka Br., generally). That failure waives the issue, and the summary judgment can be affirmed on that basis.

Despite the waiver, this Court has discretion to consider the merits. On the merits, the District Court’s claim constructions and summary judgment should be affirmed.

The exact language of the disputed claim constructions is not critical to affirming the District Court’s summary judgment of non-infringement. Kaneka’s opening brief criticizes the District Court’s claim constructions, then assumes, without explanation, that any change to those constructions—even adopting the constructions of the Texas Court—warrants remand. (Kaneka Br. 1-3, 16-17). But that is not the case.

Narrow constructions with respect to the oxidizing steps are appropriate because Kaneka’s ‘340 patent illogically claims a process for making *oxidized* CoQ₁₀ “on an industrial scale” by first making the more-difficult-to-produce

⁶ Kaneka named certain alleged distributing defendants, including Pacific Rainbow International Inc. (“PRI”) and Maypro Industries, Inc. (“Maypro”).

reduced CoQ₁₀. The claims require culturing microorganisms to produce an initial percentage of at least 70 mole % reduced CoQ₁₀. Subsequent limitations require that this initially-produced reduced CoQ₁₀ be protected until a specific oxidizing step. Certain claims provide this protection by requiring extracting the reduced CoQ₁₀ under an inert gas atmosphere or in a sealed tank. The claim language also explicitly requires a certain order to the oxidizing and extracting steps, thereby disclaiming oxidation at other points in the claimed process, particularly during extraction.

The District Court's claim constructions are based on the claim language and intrinsic record and should be upheld. (A3571-87). As to the limitations relied upon in granting summary judgment:

- An “inert gas atmosphere” should not oxidize reduced CoQ₁₀;
- A “sealed tank” is, as a matter of plain and ordinary meaning, both sealed and a tank; and
- Oxidizing the reduced CoQ₁₀ must be done at a specific ordered step, either before extraction or after extraction—thereby requiring protection from oxidation until that oxidation step and substantially complete oxidation as a result of that oxidation step—and precluding oxidation during extraction.

**REDACTED: CONTAINS MATERIAL
SUBJECT TO PROTECTIVE ORDER**

The dispute over the “culturing” claim phrase relates to how the 70 mole % reduced CoQ₁₀ is measured and need not be resolved unless the case is remanded. Fairness to the public requires that the patent’s “standard” assay be a safe harbor. The District Court’s construction is supported by the patent’s specification, which describes a “standard” assay to determine whether the cultured microorganisms have produced 70 mole % reduced CoQ₁₀, and further supported by evidence from the ITC showing that [REDACTED]

[REDACTED]

[REDACTED]. (A64-81; A3571-87).

Kaneka’s claim constructions contradict the plain meaning of the claims:

- Claims 1 and 11 require extracting under an “inert gas atmosphere.” Kaneka interprets “inert gas atmosphere” to be reactive enough to oxidize reduced CoQ₁₀.
- Claims 22 and 33 require extracting in a “sealed tank.” Kaneka interprets the claimed “sealed tank” to be un-sealed and the “tank” to include equipment that is not a tank (*i.e.*, a solvent condenser).
- Kaneka asserts the order of the oxidizing and extracting steps does not matter, but the plain language of the claims requires an order:
 - “oxidizing thus-obtained reduced coenzyme Q₁₀ to oxidized

coenzyme Q₁₀ and then extracting the oxidized coenzyme Q₁₀”

(claims 1 and 22) requires oxidation before extraction;

- “extracting the reduced coenzyme Q₁₀ . . . and oxidizing the extracted reduced coenzyme Q₁₀” (claims 11 and 33) requires extracting before oxidation.
- All of the claims are directed to “a process of producing on an industrial scale the oxidized coenzyme Q₁₀ . . .” Contrary to “an industrial scale,” Kaneka’s construction would be met by producing a miniscule amount of oxidized CoQ₁₀ in the recited oxidizing step.
- All of the claims require “culturing” microorganisms to produce “at least 70 mole % reduced coenzyme Q₁₀ . . .” Kaneka’s construction vitiates this limitation, interpreting the claims to be met if the “at least 70 mole % reduced” is entirely lost to oxidation before any other recited step.

The District Court’s summary judgment of non-infringement is based on undisputed evidence originally developed during the ITC investigation, including Kaneka’s inspection of Shenzhou’s manufacturing plant, Kaneka’s expert analyses of Shenzhou process samples taken during that inspection, and Kaneka’s deposition of Shenzhou’s corporate representatives. (A5209-36).

**REDACTED: CONTAINS MATERIAL
SUBJECT TO PROTECTIVE ORDER**

Shenzhou's process for making oxidized CoQ₁₀ [REDACTED]

[REDACTED]. [REDACTED]

[REDACTED]

[REDACTED]. (A5221-22; A5972-6036).

During Shenzhou's extraction, Kaneka's own experts observed [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]. (A5775; A6659 at Table 6; A6097 at Table 3; A5972-

6036). At the ITC, Kaneka's expert admitted that [REDACTED]

[REDACTED]. (A6067-69).

Because the undisputed evidence shows that Shenzhou's process does not meet the "inert gas atmosphere" limitation, the "sealed tank" limitation, and the "oxidizing" in order limitations, the District Court's summary judgment of non-infringement should be affirmed.

V. ARGUMENT

A. Applicable Standards of Review

There are two standards of review relevant to this appeal: (1) the standard for reviewing claim constructions; and (2) the standard for reviewing the grant of

⁷ There is no evidence that [REDACTED]

[REDACTED].

summary judgment. Kaneka's opening brief fails to address the standard for reviewing a grant of summary judgment.

1. Standard of Review for Claim Construction

To the extent Kaneka's statement of the standard of review for claim construction quotes the cases, it actually supports the District Court's analysis.

Kaneka properly notes the "heavy presumption" that a claim term should be given its ordinary meaning. Kaneka Br. at 38, *citing CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

Kaneka notes the primacy of intrinsic evidence over extrinsic evidence. "The court turns to extrinsic evidence only when the intrinsic evidence is insufficient to establish the clear meaning of the asserted claims." *Zodiac Pool Care, Inc. v. Hoffinger Ind., Inc.*, 206 F.3d 1408, 1414 (Fed. Cir. 2000) (Kaneka Br. at 39). "Although extrinsic evidence can shed useful light on relevant art, it is considered less significant than the intrinsic record in determining the operative meaning of claim language." (Kaneka Br. at 40, *citing Phillips v. AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005)). "[T]he court may not use extrinsic evidence to arrive at a claim construction that is clearly at odds with the construction mandated by the intrinsic evidence." *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 971 (Fed. Cir. 1999) (Kaneka Br. at 40).

Kaneka also notes that the embodiments should generally not be read into the claims. (Kaneka Br. at 40-41 (“particular embodiments and examples appearing in the specification will *not* generally be read into the claims.”)), *citing Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir. 1998) (Kaneka’s emphasis.))

But Kaneka then provides a vague and canned critique of the District Court’s constructions, suggesting that they are somehow contrary to the plain meaning, they are premised on extrinsic evidence, or they read embodiments into the claims. Kaneka’s brief has it exactly backwards:

- It is Kaneka, not the District Court, seeking to contradict the specification’s explicit definition of “atmosphere of inert gas” by introducing an extrinsic expert declaration to expand the specification’s mere use of the words “safe operation” into otherwise unstated concerns about solvents exploding.
- It is Kaneka, not the District Court, seeking to contradict the plain meaning of “sealed tank” by reading the Figure 1 embodiment into the claim, even though Figure 1 plainly does not disclose a sealed tank.
- It is Kaneka, not the District Court, denying the plain language of the claims that requires the claimed oxidizing steps be performed in order.

2. Standard of Review for Summary Judgment

Where an issue is not unique to patent law, the Federal Circuit applies the law of the regional circuit from which the case arises. *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350, 1354 (Fed. Cir. 2013).

The Ninth Circuit reviews grants of summary judgment *de novo*. *Brain Life, LLC v. Elekta Inc.*, 746 F.3d 1045, 1052 (Fed. Cir. 2014); *see also Allergan, supra at 1354*. Summary judgment is appropriate if, viewing the evidence in the light most favorable to the non-moving party, the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law. *See Fed. R. Civ. P. 56(a)*; *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). “Summary judgment of non-infringement is also appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial.” *TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002).

Patent infringement requires a two-step analysis. First, this Court must determine as a matter of law the correct scope and meaning of a disputed claim term. *CCS Fitness, supra at 1365*. The Federal Circuit reviews this aspect of the infringement analysis *de novo*. *CCS Fitness, supra at 1365*. Second, the analysis requires a comparison of the properly construed claims to the accused device, to

see whether that device contains all the limitations, either literally or by equivalents, in the claimed invention. *CCS Fitness, supra* at 1365.

“Whether the accused device contains an element corresponding to each claim limitation or its equivalent is a question of fact, which, on summary judgment, is a question [this Court] review[s] to determine whether a material factual issue remains genuinely in dispute.” *TechSearch, supra* at 1369-70.

“[A]n appellate court may affirm a judgment of a district court on any ground the law and the record will support so long as that ground would not expand the relief granted.” *Glaxo Grp. Ltd. v. TorPharm, Inc.*, 153 F.3d 1366, 1371 (Fed. Cir. 1998). Indeed, even when there is an error in claim construction, such error does not warrant reversal of summary judgment when the moving party remains entitled to summary judgment. *See Innovad Inc. v. Microsoft Corp.*, 260 F.3d 1326, 1334-35 (Fed. Cir. 2001) (although summary judgment “should ordinarily be vacated or reversed if based on a claim construction that this court determines includes error[,]” “if the record discloses no genuine issues of material fact and the movant remains entitled to judgment as a matter of law despite an error in claim construction, this court can affirm the district court's grant of summary judgment”).

B. Kaneka Has Waived Its Challenge to the Summary Judgment Order

Kaneka's opening brief fails to explain why the District Court's summary judgment of non-infringement is wrong. Indeed, the District Court's summary judgment did not even make Kaneka's statement of the issues.

Accordingly, Kaneka has waived its right to challenge the propriety of the District Court's grant of summary judgment of non-infringement in favor of Shenzhou by failing to include any argument concerning such grant of summary judgment in its opening brief. Federal Rule of Appellate Procedure 28(a)(8)(A) requires that the argument section of an appellant's opening brief contain the "appellant's contentions and the reasons for them, with citations to the authorities and parts of the record on which the appellant relies[.]"

Pursuant to this rule, this Court has held that a party waives an argument not raised in its opening brief. *See Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 833 (Fed. Cir. 2010); *see also Amado v. Microsoft Corp.*, 517 F.3d 1353, 1360 (Fed. Cir. 2008) ("[a]n issue that falls within the scope of the judgment appealed from but is not raised by the appellant in its opening brief on appeal is necessarily waived"); *United States v. Great Am. Ins. Co. of New York*, 738 F.3d 1320, 1328 (Fed. Cir. 2013) ("It is well established that arguments that are not appropriately developed in a party's briefing may be deemed waived").

Notably, “mere statements of disagreement with the district court as to the existence of factual disputes do not amount to a developed argument.” *SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006). Further, “arguments may not be properly raised by incorporating them by reference from the appendix rather than discussing them in the brief.” *Graphic Controls Corp. v. Utah Med. Products, Inc.*, 149 F.3d 1382, 1385 (Fed. Cir. 1998). Similarly, arguments raised in footnotes are not preserved. *SmithKline Beecham, supra* at 1320.

Although this Court has discretion to address an argument not properly raised by an appellant in its opening brief if disregarding the argument would result in an unfair procedure, exercise of this discretion does not apply where the appellant “clearly understood the issue [] but simply never made the argument.” *Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 833 (Fed. Cir. 2010). This is the case here.

In the matter at hand, the “issues for review”—as set forth by Kaneka—do not include whether the District Court erred in granting summary judgment of non-infringement in favor of Shenzhou. Instead, the “issues for review” are limited to whether the District Court erred with respect to its claim construction order.

Kaneka’s brief makes clear that Kaneka knows this is an appeal not only from the District Court’s claim construction order, but also from “a final judgment,

dated March 27, 2014, which implemented two orders which (a) granted in part Xiamen Kingdomway Group Company's Motion for Summary Judgment of Non-infringement of U.S. Patent No. 7,910,340 and (b) granted in part Shenzhou Biology and Technology Co. Ltd.'s Motion for Summary Judgment of Non-infringement of U.S. Patent No. 7,910,340 . . .” (Kaneka Br. at 1). By failing to address the propriety of the District Court's grant of summary judgment of non-infringement in favor of Shenzhou, Kaneka has waived the issue.

C. This Court Should Affirm the District Court's Claim

Constructions

1. An “Inert Gas Atmosphere” Should Not Oxidize Reduced Coenzyme Q₁₀

The District Court construed “inert gas atmosphere” to mean, “a gas atmosphere that is free or substantially free of oxygen and reactive gases.” (A3578). This construction should be affirmed because it is based on the patent specification's disclosure that an “atmosphere of inert gas” is an example of a “deoxygenized atmosphere” and of a “condition that reduced coenzyme Q₁₀ is protected from an oxidation reaction.”

The '340 patent specification discloses “an atmosphere of inert gas” as follows: “As ‘the condition that *reduced coenzyme Q₁₀ is protected from an oxidation reaction*’ means, for example, a *deoxygenized atmosphere* (an

atmosphere of inert gas such as nitrogen gas, carbon dioxide gas, helium gas, argon gas, or hydrogen gas, reduced pressure, a boiling condition) . . .” (A74, col. 16:25-39) (emphasis added).

The above portion of the specification directly supports the District Court’s construction requiring that the inert gas atmosphere be “free or substantially free of oxygen and reactive gases.” (A3577-78). The specification identifies hydrogen gas as an inert gas because hydrogen gas will not oxidize reduced CoQ₁₀. (A74, col. 16:25-39).

The specification is explicit that “an atmosphere of inert gas” is intended as a “condition that reduced coenzyme Q₁₀ is protected from an oxidation reaction.” (A74, col. 16:35-39). No part of the patent specification identifies any other purpose for an “inert gas atmosphere.”

The District Court’s construction is also consistent with the claims. Independent claim 11 provides for “extracting the reduced coenzyme Q₁₀ by an organic solvent under an inert gas atmosphere.” (A3577-78; A74, col. 25:3-4). Here, the inert gas atmosphere protects the reduced CoQ₁₀ from oxidation during extraction, preserving it for the subsequent oxidizing step: “oxidizing the extracted reduced coenzyme Q₁₀. . .” (A74, col. 25:5). The District Court’s construction is also consistent with claim 1’s dependent claim 9, which further limits the “inert gas atmosphere” as comprising nitrogen, one of the listed “inert gases” in the

specification. (A3571-87).

Kaneka's proposed construction—"a gas atmosphere that is less readily reactive with the solvent"—reads "inert" out of "inert gas atmosphere." Kaneka asserts that the true purpose of the "inert gas atmosphere" is safety, and Kaneka seeks a construction that permits the "inert gas atmosphere" to oxidize reduced CoQ₁₀, so long as it does not blow up the factory.

Kaneka hopes that alarming rhetoric about the hazards of solvents will suggest that a safe atmosphere must be inert, but Kaneka's own evidence shows that even ambient air can be a "safe" atmosphere. Kaneka submitted the Declaration Of Dr. Jeffrey D. Kittendorf in opposition to Shenzhou's motion for summary judgment of non-infringement (A7822-7827) to explain the fire hazard posed by solvents. But Dr. Kittendorf admits that a spark is required to initiate combustion. (A7822-7827). Accordingly, absent a spark, ambient air is "safe." Consistent with Dr. Kittendorf's admission, Shenzhou offered a demonstrative film showing that, in the absence of a spark, hexane can be safely poured in open air. (A6289).

Realizing that ambient air is unlikely to qualify as an "inert gas atmosphere," Kaneka argues that what is needed is an atmosphere that will not allow combustion even with a spark, but that construction still allows a significant amount of oxygen to be present. For hexane, Kaneka asserts a "safe" condition requires reducing the

oxygen level to 12% oxygen (Kaneka Br. at 46), but 12% oxygen is still *two-thirds* of the oxygen in ambient air, which contains 18% oxygen. (Kaneka Br., at 46; A7825-7827).

The '340 patent specification's express definition of "atmosphere of inert gases" cannot be overcome by Kaneka's extrinsic evidence respecting the point of combustion for various solvents. Indeed, the patent's identification of notoriously dangerous hydrogen gas⁸ as an example of an inert gas contradicts Kaneka's position that inert just means safe. (A74, col. 16:35-39).

Nowhere does the patent tie an "inert gas atmosphere" to safety. Seeking intrinsic support, Kaneka mischaracterizes the following passage from the patent specification: "Incidentally, it is *not necessary* to carry out the *recovery of oxidized coenzyme Q₁₀ under 'the condition that reduced coenzyme Q₁₀ is protected from an oxidation reaction'*, which is recommended for the recovery of reduced coenzyme Q₁₀, and the recovery may be carried out in consideration of general safe operation and the like." (A75, col. 17:21-26) (emphasis added).

This passage states the obvious: in recovering oxidized CoQ₁₀, there is no need to protect reduced CoQ₁₀ from oxidation. This is obvious because the oxidized CoQ₁₀ being recovered cannot be further oxidized by ambient air.

⁸ Remember the *Hindenburg*.

Kaneka tries to read more into it, but there is nothing else.

Starting with the plain language, the passage does not even use the phrase “inert gas.” For that reason, the passage cannot define “atmosphere of inert gas” or “inert gas atmosphere.”

In fact, any connection between the passage and “inert gas atmosphere” must be premised on the phrase “the condition that reduced coenzyme Q₁₀ is protected from an oxidation reaction.” But that connection can only confirm that an “inert gas atmosphere” *is* a “condition that reduced coenzyme Q₁₀ is protected from an oxidation reaction.”

Taking an “inert gas atmosphere” as an example of a “condition that reduced coenzyme Q₁₀ is protected from an oxidation reaction,” then the passage can be fairly read to mean that an “inert gas atmosphere” is not necessary to recover oxidized CoQ₁₀. In effect, Kaneka illogically argues that because claim 1 recites extracting oxidized CoQ₁₀ under an unnecessary “inert gas atmosphere,” the phrase “inert gas atmosphere” must have some other meaning in claim 1 that makes it “necessary.”

But saying an inert gas atmosphere is not necessary is not the same as saying an inert gas atmosphere is precluded. Of course one can recover oxidized CoQ₁₀ under an inert gas atmosphere.

No rule prohibits a patentee from adding to a claim what the specification

characterizes as “unnecessary” limitations. Indeed, most dependent claims can be characterized as adding what the specification teaches are unnecessary limitations.⁹ The dependent claims of the ‘340 patent itself illustrate this. *See, e.g.*, claims 2, 3, 5, and 9 (requiring extracting with a hydrophilic solvent, extracting with a hydrophobic solvent, oxidizing with manganese oxide, and extracting under nitrogen gas).

“Unnecessary” limitations (like dependent claims) are frequently added to avoid prior art (known and not-yet-known). Here, “inert gas atmosphere” was added by amendment in response to a prior art rejection. (A12786-12802, 13181-13205).

Kaneka does not address claim 11, which provides for extraction of *reduced* CoQ₁₀ under an inert gas atmosphere. The necessity of an inert gas atmosphere as “a condition that reduced CoQ₁₀ is protected from an oxidation reaction” in claim 11 is clear: to protect the reduced CoQ₁₀ from oxidation during the extracting step.

As noted above, claim 9 depends from claim 1 and requires that the “inert gas atmosphere” comprise nitrogen. Contrary to Kaneka’s argument, claim 9 supports the District Court’s construction because nitrogen is listed in the

⁹ Whether a dependent claim limitation is truly unnecessary depends in part on how the independent claim is construed. As discussed, *infra*, respecting the oxidizing steps, claim differentiation is a mere presumption that the dependent claims have a more narrow scope than the independent claim. *See Seachange, supra* at 1368-69.

specification's definition of "inert gas atmosphere" as a "condition that reduced coenzyme Q₁₀ is protected from an oxidation reaction."

In addition, claim 20, depending from independent claim 11 (providing for extracting reduced CoQ₁₀), similarly provides that the inert gas atmosphere comprises nitrogen, consistent with protecting the extracted reduced CoQ₁₀ from oxidation.

Applying different constructions to claims 1 and 11 is improper. Nothing in the patent or the claims suggests two different meanings for "inert gas atmosphere." In general, a claim term in a single patent should be construed to mean the same thing wherever it appears. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001); *CVI/Beta Ventures, Inc. v. Tura LP*, 112 F.3d 1146, 1159 (Fed. Cir. 1997) ("[W]e are obliged to construe the term 'elasticity' consistently throughout the claims.")

The Texas Court construed "extracting -- under an inert gas atmosphere" to mean "extracting--under a gas atmosphere that is substantially free of reactive gases." (A3337). This construction is actually substantively similar to the District Court's construction, which merely added a specific reference to oxygen. Oxygen, of course, is indisputably a "reactive gas." (Kaneka Br. at 34) ("Kaneka's

definition allows for a percentage of oxygen, a reactive gas”¹⁰

2. A “Sealed Tank” Should Be Sealed and a Tank

Independent claims 22 and 33 require extracting “in a sealed tank.” The District Court construed “sealed tank” to mean “a tank that is closed to prevent the entry or exit of materials.” Claim Construction Order at 9 (A3579). This construction should be affirmed as the plain and ordinary meaning of “sealed tank.”

The “sealed tank” limitation was added and argued to distinguish the Kondo and Yoshida references. (A13209-13228).

The phrase “sealed tank” does not appear in the specification of the ‘340 patent, nor does it appear in any of the original claims. (A64-81). Though not ripe here, the absence of the phrase obviously raises issues as to whether the claim is adequately supported by the specification.

Lacking any explicit intrinsic source, “sealed tank” must be construed to have its plain and ordinary meaning: a tank that is sealed. This is consistent with the District Court’s construction: closed to prevent the entry or exit of materials. Kaneka does not dispute this is the plain and ordinary meaning of “sealed.” (*See*

¹⁰ While Kaneka concedes that oxygen is a reactive gas, by agreeing with the Texas Court’s construction (Kaneka Br. at 47), Kaneka implies that somehow “substantially free of reactive gases” permits more oxygen than the District Court’s construction. On its face, Kaneka’s position makes no sense.

Kaneka Br. at 34-35; A3571-87).¹¹

To avoid summary judgment of non-infringement of independent claims 22 and 33 and their dependent claims, Kaneka needs a construction of “sealed tank” that is not sealed and not a tank. To read on Shenzhou’s process, Kaneka needs a construction that permits extracting in a tank having an open exhaust that leads to another piece of equipment (a condenser) having a non-extracting function (solvent recovery).

The fundamental error in Kaneka’s analysis is identifying Figure 1 as an embodiment of a “sealed tank.” Kaneka reasons backwards that because the claims use the term “sealed tank,” there must be a “sealed tank” somewhere in the specification. Since “tanks” are shown in Figure 1, they must be the claimed “sealed tanks.” Despite the obvious absurdity, Kaneka concludes that since the tanks in Figure 1 are shown exchanging contents, the claimed “sealed tanks” are not sealed at all but instead can also exchange contents.

If claim construction logic worked as Kaneka argues, it would be impossible to hold that any claim is not supported by its specification—one would just

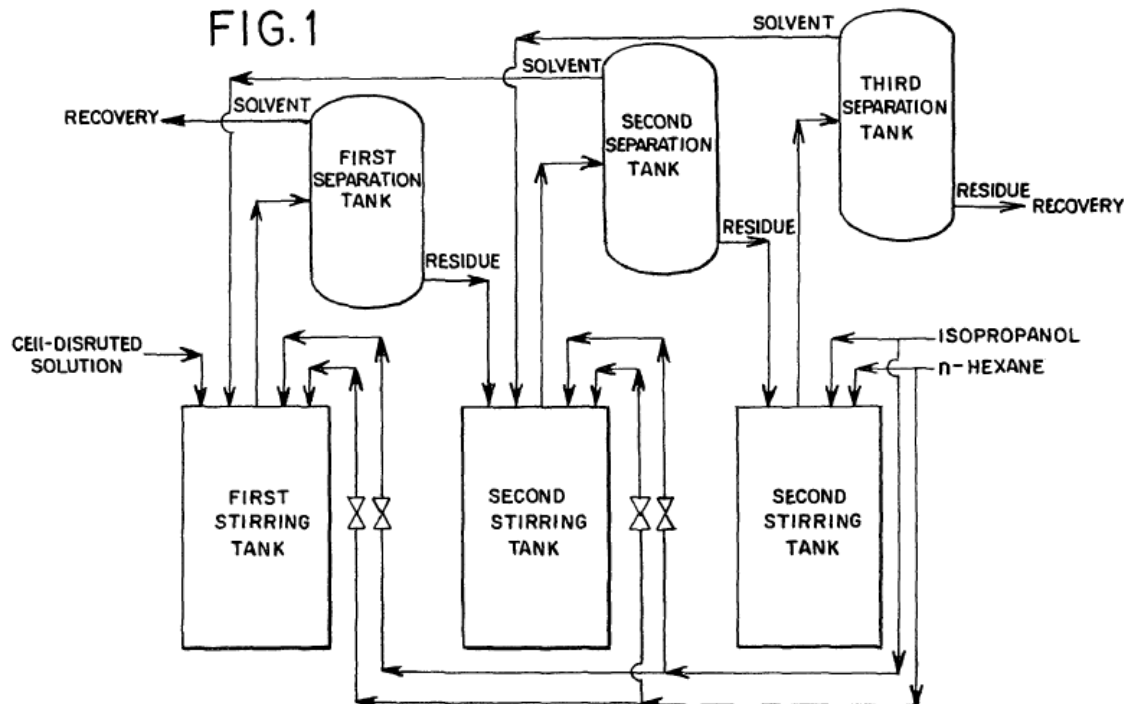
¹¹ The District Court relied upon ALJ Rogers’s analysis. (A3579). ALJ Rogers relied on: A15741-15751 (Initial Determination); A64-81, at col. 9:22-26, 9:33-42, 20:65-21:1, 22:2-5, 23:20-25, 23:55-26:64 and Fig. 1 (‘340 patent); A15676 (Witness Statement of Alfred Spormann); A13209-228 (August 27, 2010 Amendment); and A16112 (Merriam-Webster’s Collegiate Dictionary).

interpret the claims to mean something the specification happened to say. That is not the law, as shown by any number of cases holding claims invalid for lack of specification support. *See, e.g., ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 943 (Fed. Cir. 2010) (determining that the asserted claims were invalid for lack of enablement under 35 U.S.C. § 112).

As already noted, the words “sealed tank” do not appear in the specification, and nothing in Figure 1 (reproduced below) is described as or looks like a “sealed tank.” Instead, Figure 1 is described as a “countercurrent 3-step continuous extraction apparatus.” (A66). This creates multiple problems for Kaneka’s proposed constructions:

- First, nothing in the illustrated “*continuous* extraction apparatus” can be construed as a “sealed tank.” Though Figure 1 has features labeled “tank,” they all have arrowed connecting lines that can only be interpreted as open. Kaneka actually acknowledges that these lines are open during extracting. Kaneka Br. at 52 (“the tanks have various incoming and outgoing pipes or lines permitting the contents of the tanks to be exchanged as shown in Fig 1 below.”)
- Second, a “tank” is, on its face, more narrow than Figure 1’s “extraction apparatus,” which comprises multiple elements labeled “tank.” Accordingly, the claimed “tank” cannot be construed to

include additional equipment outside the “tank.”



Kaneka’s proposed definition, “a tank that substantially prevents direct exposure of its contents to the atmosphere,” is too vague to capture the plain and ordinary meaning of “sealed.” The qualifications “substantially” and “direct” are needlessly ambiguous compared to the plain and ordinary meaning of “sealed.” For those reasons, Kaneka’s proposed definition was even rejected by the Texas Court. (*See* Kaneka Br. at 16, 21).

Kaneka again asserts that safety, not protection from oxidation, is the purpose of the “sealed tank.” Since the words “sealed tank” do not appear in the patent, there is no intrinsic support for Kaneka’s position. (A64-81). Strangely, Kaneka cites with apparent approval the Texas Court noting that the specification

does not link safety to sealed tank. (Kaneka Br. at 20-21, 50, quoting Judge Gilmore (“the patent specification does not specifically link sealed tanks to safety concerns.”)).

As with “inert gas atmosphere,” the alleged safety purpose is intended to allow the “sealed tank” to be unsealed, so long as it does not blow up the factory or allow toxic fumes into the atmosphere. Again, just because the factory does not blow up or pollute the environment does not mean the “sealed tank” limitation has been met.

The “sealed tank” limitation was added and argued to distinguish Kondo and Yoshida. (A13209-228). As a matter of plain and ordinary meaning, a sealed tank is different from a safe tank. Not all sealed tanks are safe, and not all safe tanks are sealed.

Indeed, Kaneka is correct that, as construed by the District Court, a “sealed tank” containing volatile solvent may be very dangerous. But one cannot extrapolate the specification’s mention of the word “safe” into a broadening of the plain and ordinary meaning of the claimed “sealed tank.” No rule of patent prosecution or construction requires an invention be safe at all, let alone justifies broadening the plain and ordinary meaning of “sealed tank” to include “unsealed” features just because the specification uses the word “safe.”

Kaneka tries to bootstrap the specification support for certain dependent

claim limitations into intrinsic support for interpreting “sealed tank” to mean the tanks in Figure 1. Claims that depend on the “sealed tank” independent claims 22 and 33 recite a “continuous” and “countercurrent multistage extraction.” Claims 27, 28, 39, 40. (Kaneka Br. at 49-54). In effect, Kaneka argues that because Figure 1 shows a “continuous countercurrent multistage extraction apparatus” as recited in the dependent claims, it must also show the “sealed tank” of the independent claims. *Id.*

But the lack of support for the “sealed tank” limitation of *independent* claims 22 and 33 is a problem that necessarily infects all of their dependent claims. The dependent claims merely inherit the “sealed tank” limitation; they do not support it. Accordingly, that Figure 1 supports the dependent claims’ “continuous” and “countercurrent multistage extraction” limitations does not mean that Figure 1 also supports the “sealed tank” limitation in independent claims 22 and 33.

Kaneka inappropriately invokes claim differentiation to support contradicting the plain and ordinary meaning of “sealed tank.” But claim differentiation cannot turn Figure 1 into support for “sealed tanks,” and without intrinsic support, the “sealed tank” limitation must be given its plain and ordinary meaning.

The claim differentiation doctrine does not allow the “sealed tank” limitation in independent claims 22 and 33 to be broadened beyond its plain and ordinary

scope to accommodate the dependent claims. The claim differentiation doctrine “can not broaden claims beyond their correct scope, determined in light of the specification and the prosecution history and any relevant extrinsic evidence.” *Seachange Int’l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1369 (Fed. Cir. 2005). The doctrine “only creates a presumption that each claim in a patent has a different scope; it is not a hard and fast rule of construction.” *Id.*¹²

The Texas Court construed “extracting--in a sealed tank” to mean “extracting the oxidized[sic] coenzyme Q₁₀ by an organic solvent in a tank that prevents exposure of its contents to the atmosphere.” (A3341-42). The Texas Court’s reasoning suffers the same logical error as Kaneka’s argument, assuming that because the claims recite a “sealed tank,” then Figure 1 must show a sealed tank. (See Kaneka Br. at 20-22, 24-25, 29-30, 34-35, 50, quoting Judge Gilmore (“Although Figure 1 is not captioned or described as depicting sealed tanks . . . Because it is the only picture of tanks contained in the patent, it supports Kaneka’s position that sealed tanks would allow for the entry and exit of substances.”))

¹² See also *Starhome GmbH v. AT&T Mobility LLC*, 743 F.3d 849, 858 (Fed. Cir. 2014 (“[t]he doctrine is not a hard and fast rule, but instead ‘a rule of thumb that does not trump the clear import of the specification’”), quoting *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1332 (Fed. Cir. 2009)); and *Saffran v. Johnson & Johnson*, 712 F.3d 549, 563 (Fed. Cir. 2013), *cert. denied*, 134 S. Ct. 1023 (2014) (“we have long held that a patentee cannot rely on claim differentiation to broaden a means-plus-function limitation beyond those structures specifically disclosed in the specification”).

Because the plain meaning of “sealed” is that nothing can enter or exit, and there is no intrinsic support for a different construction, the District Court’s construction should be upheld.

3. The Oxidizing Steps Must Be Done in Proper Order

The District Court recognized that the claims limit the order of the oxidizing and extracting steps.¹³ (A3571-87). This necessarily means that the claims preclude oxidizing or extracting out of the claimed order—any other result would vitiate the claimed order of steps. Most significantly, the claimed order of steps also precludes oxidizing during extraction.

An important context to the oxidizing steps is the amendment added to all claims: that the claimed method is to produce oxidized CoQ₁₀ “on an industrial scale.” (A13206-13234). Again, this limitation was added to avoid the Kondo and, especially, Yoshida references. (A13209-13228). Given the “industrial scale” amendment, the oxidizing steps cannot be met by anything less than substantially complete oxidation of the initially-produced at least 70 mole % reduced CoQ₁₀.

The District Court interpreted the oxidizing steps as follows:

¹³ In fact, the District Court found that all of the steps are ordered (A3576-85), but the ordering of the oxidizing and extracting steps is sufficient to support the District Court’s summary judgment of non-infringement.

- Independent claims 1 and 22: “oxidizing thus-obtained reduced coenzyme Q₁₀ to oxidized coenzyme Q₁₀” means “actively converting all or substantially all of the reduced coenzyme Q₁₀ obtained from the disruption step to oxidized coenzyme Q₁₀ in a step before beginning the extraction step.”
- Independent claims 11 and 33: “oxidizing the extracted reduced coenzyme Q₁₀ to oxidized coenzyme Q₁₀” means “actively converting all or substantially all of the extracted reduced coenzyme Q₁₀ obtained from the disruption step to oxidized coenzyme Q₁₀ in a separate step after the extraction step has been performed.”

Claim Construction Order at 15-16 (A3585-86).

Although steps in a method or process claim generally need not be performed in the same order listed in the claims, the language of the claims may require that steps be performed in a certain order. *See, e.g., Interactive Gift Exp., Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1342 (Fed. Cir. 2001) (setting forth the test for determining when steps in a method claim should be construed to be performed in the stated order). The modifiers found in the claims—*e.g.*, “thus-obtained,” “then extracting,” and “the extracted reduced”—require that the oxidizing and extracting steps be performed in the order listed.

On their face, the claims unambiguously limit the order of oxidizing and

extracting:

- Independent claims 1 and 22 explicitly require oxidizing first; then extracting: “*oxidizing* thus-obtained reduced coenzyme Q₁₀ to oxidized coenzyme Q₁₀ and *then extracting the oxidized* coenzyme Q₁₀” (emphasis added). The phrase “oxidizing *thus-obtained reduced* coenzyme Q₁₀” unambiguously requires oxidizing the reduced CoQ₁₀ “obtained” during the preceding cell disrupting step, and the phrase “*then extracting the oxidized* coenzyme Q₁₀” unambiguously refers to subsequently extracting the formerly reduced but now-oxidized CoQ₁₀.¹⁴ The claim language cannot be met if the steps are reordered: one cannot “*then extract[] the oxidized* coenzyme Q₁₀” before the reduced is oxidized.
- Independent claims 11 and 33 explicitly require extracting first, then oxidizing: “extracting the reduced coenzyme Q₁₀ . . . and *oxidizing the extracted reduced* coenzyme Q₁₀....” (emphasis added). The phrase “oxidizing the extracted reduced CoQ₁₀” is plainly limited to oxidizing reduced CoQ₁₀ that has already been extracted. Again, the

¹⁴ The antecedent basis of “*the oxidized* coenzyme Q₁₀” to be extracted is the product of “oxidizing thus-obtained reduced coenzyme Q₁₀ to oxidized coenzyme Q₁₀.” This is because the claims never explicitly refer to oxidized coenzyme Q₁₀ recovered directly from the cells.

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claim language cannot be met if the steps are reordered: one cannot “oxidize *the extracted* reduced coenzyme Q₁₀” if it has not already been extracted.

The claim language is so compelling that even Kaneka cannot avoid admitting this reading of the claims: “claim 1 calls for oxidation before extraction and claim 11 calls for extraction before oxidizing.” (Kaneka Br. at 55).

The oxidizing step must oxidize substantially all of the reduced CoQ₁₀, both because the claims all require that oxidized CoQ₁₀ is produced “on an industrial scale” and because, logically, whatever oxidation is going to happen must either be before (claims 1 and 22) or after (claims 11 and 33) the extracting step.

Given the explicit ordering of the oxidizing and extracting steps, oxidizing during extracting is necessarily precluded by the claim language. Since the extracting steps specifically require extracting either “the oxidized” (claims 1 and 22) or “the reduced” (claims 11 and 33) CoQ₁₀, the claimed extracting step must be either before or after substantially all of the reduced CoQ₁₀ has been oxidized.

The District Court also interpreted the oxidizing steps to require “actively converting” the reduced CoQ₁₀ to oxidized CoQ₁₀ in a “separate step.” This requirement is supported by the specification, particularly the examples, which all use an oxidizing agent to achieve substantially complete oxidation in a single, separate step. (A3571-87; A64-81). Furthermore, [REDACTED]

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[REDACTED]. (A8817-

23). Accordingly, this aspect of the claim constructions should be affirmed.

Kaneka seeks “no construction” of the oxidizing steps, intending that the oxidizing steps be met by any amount of oxidation at any point in the process. (*See, e.g.*, Kaneka Br. at 37). But such an interpretation would lead to absurd results.

If any amount of oxidation met the oxidizing step, then a process whose culturing step produced 99 mole % reduced CoQ₁₀ would meet the claim limitation by oxidizing to only 98 mole % reduced CoQ₁₀. The resulting 2 mole % oxidized CoQ₁₀ would make a mockery of producing oxidized CoQ₁₀ “on an industrial scale.”

Allowing partial oxidizing would also vitiate the explicit ordering of the extracting and oxidizing steps. Again, starting with a culturing step producing 99 mole % reduced CoQ₁₀, oxidizing “before” extracting could be met by oxidizing to only 98 mole % reduced CoQ₁₀, followed by extracting and then by an “unclaimed” oxidizing of the remaining reduced CoQ₁₀. Thus, *de minimis* oxidizing, extraction, and more oxidizing would perversely meet the “ordered” claim steps for oxidizing then extracting. Where the steps are ordered, performing the steps in a different order must be precluded. *See, e.g., Interactive Gift, supra* at

1342.

Allowing oxidizing at any time also vitiates the threshold requirement that the microorganisms be cultured to produce at least 70 mole % reduced CoQ₁₀. In Kaneka's view, once the 70 mole % reduced CoQ₁₀ milestone is achieved, *even in the middle of the culturing step*, the reduced CoQ₁₀ can be completely oxidized by, for example, changing the culturing conditions. But this is no different in effect from culturing microorganisms to make oxidized CoQ₁₀ in the first place.

Because the ordering of the claim steps is based on the plain language of the claims, to the extent the specification discloses other step orders, those other step orders have simply not been claimed. Accordingly, it does not matter that, as Kaneka points out, the specification discloses that "cell disruption and extraction can be carried out at the same time." (Kaneka Br. at 12-13; A71, col.9:19-21).

Kaneka argues that because the claimed steps are introduced with the word "comprising," the order of steps cannot be ordered. (Kaneka Br. at 47-48).

Kaneka's argument has two flaws:

1. The "comprising" introduction cannot rewrite the language of the steps themselves that require an order. *See Loral Fairchild Corp. v. Sony Corp.*, 181 F.3d 1313, 1322 (Fed. Cir. 1999) (in connection with a process claim whose six steps were prefaced by the phrase "comprising the steps of," determining that "[a]lthough not every process claim is

limited to the performance of its steps in the order written, the language of the claim, the specification and the prosecution history support a limiting construction in this case” such that “the claim was properly construed as only covering a fabrication process where insulation is formed **prior** to ion implantation”) (emphasis added); and *Interactive Gift, supra* at 1342.

2. The District Court’s construction does not make “comprising” surplusage, because additional unclaimed steps—that are not also one of the claimed steps—may still be within the claim scope. See *Medichem, S.A. v. Rolabo, S.L.*, 353 F.3d 928, 933 (Fed. Cir. 2003) (“‘The transition ‘comprising’ in a method claim indicates that the claim is open-ended and allows for additional steps’”), quoting *Invitrogen Corp. v. Biocrest Mfg., L.P.*, 327 F.3d 1364, 1368 (Fed. Cir. 2003) (citations omitted).¹⁵

In its discussion of the “culturing” step, Kaneka argues that the steps are not ordered because “oxidation is continually occurring in the culturing step.” (Kaneka Br. at 56). The statement and subsequent argument confuse the cycle of oxidation/reduction occurring in living cells with the claimed oxidizing steps after

¹⁵ Kaneka contrasts the introduction “consisting of” (Kaneka Br. at 47-48), but fails to point out that “consisting of” would also preclude any step not claimed. (Kaneka Br. at 47-48).

the cells are killed.

Given the threshold 70 mole % reduced CoQ₁₀ limitation, the claimed oxidizing step must refer to a subsequent decrease in the mole % reduced CoQ₁₀. Requiring that the oxidizing step occur in proper order just means that any reduction in the mole % of reduced CoQ₁₀ must happen at the claimed point in the process, *i.e.*, after “culturing . . . to obtain” cells meeting the 70 mole % reduced CoQ₁₀ limitation.

In contrast, Kaneka’s reference to “oxidation . . . continually occurring in the culturing step” seems to be referring to the living cells’ use of CoQ₁₀, which involves cycling individual molecules through oxidation and reduction. (Kaneka Br. at 56; A64-81). Kaneka obliquely points out that during culturing, more cells are being produced, so of course the total molecules/moles of all coenzymes Q₁₀ (including both oxidized and reduced) increases. (Kaneka Br. at 12-13, 47-57).

Kaneka’s argument neglects that the claim limitation is a ratio: the mole % reduced CoQ₁₀ compared to all coenzymes Q₁₀. Accordingly, any production of oxidized CoQ₁₀ during culturing (even by the cells’ cyclic oxidation of reduced) that does not *decrease* the mole % reduced is not within the claimed oxidizing steps. So long as reduced CoQ₁₀ is being produced (including by the cells’ cyclic reduction of oxidized) at least fast enough to maintain the mole % reduced CoQ₁₀, the “continual” oxidation on a molecular level does not affect the claim limitation

and is not the claimed oxidizing step.

The living cells' oxidation-reduction cycling is completely irrelevant after the cells have been killed—either by disruption (claims 1 and 22) or extraction (claims 11 and 33). The claimed oxidizing steps all follow cell death. Once the cells are dead, the patent specifically teaches that the reduced CoQ₁₀ obtained from the dead cells can be protected from oxidation by using, for example, an “atmosphere of inert gas.” This is because after cell death, there is no effective agent within the process material for oxidizing the reduced CoQ₁₀.¹⁶

The real obstacle to Kaneka's position is the claim language. The patentee chose to write these claims by reciting ordered steps. It is not hard to imagine alternative claim language that requires no order to the oxidizing and extracting steps, though such claims would necessarily be very broad, potentially invalidated by prior art disclosing any amount of oxidation at any time and an extracting step that extracts either oxidized, reduced, or both.

The Texas Court concluded no construction was needed, a holding that is not

¹⁶ The patent does not discuss, and the record below does not address, any dynamic oxidation-reduction cycling of coenzyme Q₁₀ in the dead cells or after extraction. That is reason enough to neglect it. But even if there were such cycling, again, because the claim limitation is a ratio, the oxidizing steps are properly viewed as requiring a decrease in the mole % of reduced coenzyme Q₁₀. Any post-death dynamic cycling on a molecular level that does not decrease the mole % reduced is not the claimed oxidizing step.

inconsistent with finding that the plain language limits the order of steps. Kaneka cites the Texas Court's reasoning, which included rejecting the requirement that substantially all of the reduced CoQ₁₀ be oxidized in the oxidizing step. (Kaneka Br. at 64.) But that reasoning fails to account for the "industrial scale" limitation and the explicit order of steps in the claim language, and so should be unpersuasive.

4. The Mole % Reduced Limitation of the Culturing Step Must Be Measured Using the Patent's Standard Assay

The District Court did not rely upon its construction of the "culturing" step in its summary judgment of non-infringement. (A3571-87; A14062-79). For that reason, this Court need only resolve this issue if the case is remanded.

The first step in all of the claims is culturing microorganisms to obtain microbial cells containing at least 70 mole % reduced CoQ₁₀. The District Court construed "culturing reduced CoQ₁₀ producing microorganisms . . . to obtain microbial cells containing reduced CoQ₁₀ at a ratio of not less than 70 mole % among the entire coenzymes Q₁₀" to mean "culturing reduced coenzyme Q₁₀ producing microorganisms to obtain microbial cells containing reduced coenzyme Q₁₀ at a ratio of not less than 70 mole % among the entire coenzymes Q₁₀ at a time prior to the extraction, oxidation, or disruption steps and as determined by the assay described at col.5, line 8 to line 43, and Example 1 of the '340 patent."

(A3583).

There are two disputed aspects to the District Court’s construction: step ordering and the requirement that the measurement method conform to what the patent specification characterizes as a method intended “to standardize the content and the ratio of reduced coenzyme Q₁₀ . . .” (A68, col.5:36-42.)

On its face, the 70 mole % reduced CoQ₁₀ must be achieved at the culturing step. This is apparent from the claim language: the first step of each of the claims recites “culturing . . . *to obtain microbial cells containing* reduced coenzyme Q₁₀ at a ratio of not less than 70 mole % . . .” (emphasis added). The subsequently recited steps—including disruption, oxidation, and extraction—must follow the culturing step because all may affect the mole % reduced CoQ₁₀. (A 3473-3475).

The District Court’s construction did not explicitly require that the 70 mole % reduced limitation be met at the end of the culturing step, but that is implicit in the claim language and the District Court’s finding that all of the steps—including oxidizing—be performed in order. As previously explained, the oxidizing step refers to a reduction in the mole % reduced. Once the 70 mole % limitation is “obtained” from culturing, any reduction below 70 mole % must occur at the claimed oxidizing step.

This interpretation is consistent with the specification, which provides: “The culture can be *completed* at the point when a desired amount of reduced coenzyme

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Q₁₀ is produced.” (A70, col. 8:54-55) (emphasis added.) To meet the claims, the “desired amount” must be more than 70 mole % reduced coenzyme Q₁₀. By arguing that this sentence proves “there is no specific point when 70 mole % must be reached” (Kaneka Br. at 58), Kaneka ignores the plain meaning of the word “completed”—the end of the culturing step.

This interpretation does not limit any increases in the mole % reduced during culturing, but it does prevent, for example, reading the claims on a process where, during culturing, the mole % of reduced CoQ₁₀ peaks, then decreases to less than 70 mole % of reduced CoQ₁₀ before the cells are harvested (*i.e.*, before the culturing step is completed). Kaneka’s position that the 70 mole % reduced CoQ₁₀ limitation need only be met at some point during culturing leads to the absurd result that culturing to obtain 0% reduced is permitted, so long as 70 mole % reduced is present at some point during culturing. This result is absurd because it is the same as culturing “to obtain” less than 70 mole % reduced CoQ₁₀, contrary to the plain language of the claim.

Reading into the claims a requirement that any measurement testing the 70 mole % reduced CoQ₁₀ limitation be performed using the “standard” assay set forth in the patent relates to both the practical difficulties—apparently foreseen by the inventors—in measuring the mole % reduced CoQ₁₀ and fairness to the public.

The ITC evidence decisively showed that [REDACTED]

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[REDACTED]. (A13650-13798; A6039:13-6042:10, 6043:16-6045:15, 6046:14-6051:25, 6057:11-6060:22, 6061:17-19, 6079:11-6082:8; A6109-6125 at Q. 206-235; A6138 at Q. 115, 6141-42 at Q.162, 6150-6164 at Q. 262-276, and 6158-59 at Q. 416-417; A6313-16 at Q. 174-194; A6331-6336).

Given [REDACTED]

[REDACTED], the claims would be indefinite unless limited to the use of the “standard” assay described in the specification. (A3580-83). In *Honeywell Int'l, Inc. v. International Trade Comm'n*, 341 F.3d 1332 (Fed. Cir. 2003), for example, the Federal Circuit considered the construction of a claim-limitation term that included a numeric limitation without disclosing which of multiple methods of measuring that number should be used. Three methods of measurement were known and accepted in the art, and each yielded a different measurement than the others. The court held that because the patent did not specify which method to use and because the choice of method would determine whether a product met the numeric limitation, the claim was indefinite. *Id.* at 1340. Here, because the '340 patent discloses the standardized measurement method for determining the ratio of reduced CoQ₁₀, it avoids (for this limitation) the kind of indefiniteness found in *Honeywell*. The flip side, however, is that the method disclosed must be used to determine whether the 70 mole % limitation is met. *See Rhodia Chimie v. PPG*

Industries Inc., 402 F.3d 1371, 1378 (Fed. Cir. 2005) (agreeing with the district court that the reference to the results of a certain test as provided in the written description reconciled the ambiguous claim language with the inventor's disclosure); *see also Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1366-67 (Fed. Cir. 2011) (reversing ruling of indefiniteness because the patents at issue specifically disclosed a protocol useful for measuring the limitation).

Requiring use of the '340 patent's "standard" assay is consistent with the public notice policy of patents. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996) ("The claims, specification, and file history, rather than extrinsic evidence, constitute the public record of the patentee's claim, a record on which the public is entitled to rely.") Indeed, the '340 patent's description of a "standard" assay tells the public that it can rely on the "standard" assay to determine whether a process meets the 70 mole % limitation. (A64-81). Reading the limitation into the claims is required for fairness to the public: the standard assay has to provide a safe harbor. If the standard assay were not read into the claims, then even where the standard assay indicates the limitation is not met, Kaneka would be free to experiment with different tests on samples from an accused process until it got a measurement it liked. Conversely, even where the standard assay indicates the 70 mole % reduced limitation is not met, the public

would be burdened with performing undue experimentation to determine whether some other measurement might provide a different answer.

The acknowledged prior art is also a factor in holding the patentee to its standard assay. The patent acknowledges that 60 mole % reduced was already observed (A67), so a suitable assay must distinguish 60 mole % from 70 mole % reduced. Given the variability seen at the ITC, it is just too easy to materially change the results by changing the measurement method.

Kaneka argues that the District Court's construction reads Example 1 into the claims and precludes Examples 2-8. (Kaneka Br. at 59-60) This argument confuses meeting the 70 mole % reduced CoQ₁₀ limitation with measuring whether the limitation has been met. Only Example 1 includes a measurement to determine whether the 70 mole % limitation has been met. Tables 1-3 list microorganisms that—according to the patent—will meet the 70 mole % reduced CoQ₁₀ limitation if cultured a certain way. (A64-81). The remaining examples all use listed microorganisms (*Rhodotorula glutinis* and *Saitoella complicata*, both listed in Table 2) cultured as described in the specification. (A64-81). That is the premise on which Examples 2-8 meet the 70 mole % reduced limitation.

Of course, *measuring* the mole % reduced is not itself a claim limitation. Rather, a reliable and consistent measurement is needed in court to determine whether the accused process meets the claimed 70 mole % reduced CoQ₁₀ limitation. Given the

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variability evidenced in the ITC record, using the patent's self-characterized "standard" assay is needed to avoid indefiniteness. (A3580-83; A13437-13829); *see also Honeywell Int'l, supra* at 1340; *Rhodia Chimie, supra* at 1378; and *Wellman, Inc., supra* at 1366-67.

Kaneka makes a similar error when it complains that the standard measurement requires cell disruption, even though cell disruption is not a step of certain claims. (Kaneka Br. at 60). Even though practicing certain claims does not require disruption, *testing* whether the claimed 70 mole % reduced CoQ₁₀ limitation has been met does require cell disruption in order to see how much reduced CoQ₁₀ is "contained" in the cells. At the ITC, the parties [REDACTED]

[REDACTED]

[REDACTED].

Kaneka's argument that the "can be" language makes the standard assay optional is misplaced. (Kaneka Br. at 59-60). The District Court did not rely on the "can be" language, and the words "can be" do not guarantee the existence of an alternative reliable method of measurement. (A3571-87).

Instead of "can be," the critical language from the specification is the following: "The above-mentioned measurement method is provided for the obtained result to reflect the reduced coenzyme Q₁₀ content and the ratio of reduced coenzyme Q10 among the entire coenzymes Q10 *as accurate as possible* ,

and *to standardize the content and the ratio of reduced coenzyme Q10*, which can be guaranteed at the minimum.” (A69, col.5:36-42) (emphasis added).

By characterizing the method as provided “to standardize the content and ratio of reduced coenzyme Q₁₀,” this portion of the specification tells the public that it can rely upon this method to determine whether the 70 mole % reduced CoQ₁₀ limitation is met. Where this test indicates the 70 mole % reduced CoQ₁₀ limitation is not met, it would be unfair to the public to allow Kaneka to allege infringement based on some other test.

The qualification “which can be guaranteed at the minimum” does not alter the analysis. Kaneka cannot offer the public a “standard” assay, then burden the public with undue experimentation to see if other assays might provide a different answer. The specification’s assay must be a safe harbor.

D. This Court Should Affirm the District Court’s Grant of Summary Judgment of Non-Infringement in Favor of Shenzhou

1. Undisputed Evidence Supports Summary Judgment of Non-Infringement

If the Court in its discretion chooses to review the evidence supporting the District Court’s summary judgment of non-infringement, the Court will find ample support to affirm. While the record contains a complete description of the accused Shenzhou process, the following undisputed features are sufficient support for the

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District Court's summary judgment of non-infringement (A5221-22; A5972-6036):

1. [REDACTED]
[REDACTED].
2. [REDACTED]
[REDACTED].
3. [REDACTED].
4. [REDACTED]
[REDACTED].

These facts are undisputed, based on or confirmed by Kaneka's own experts after inspection of the Shenzhou plant, Shenzhou's operating documents, and the corroborating testimony of Shenzhou's corporate representative under questioning from Kaneka's counsel.

In light of these facts, at least the following claim elements cannot be met by the Shenzhou process:

Extracting under an "inert gas atmosphere": The District Court found that Shenzhou did not meet the extracting under an inert gas atmosphere limitation of claims 1 and 11 because Shenzhou [REDACTED]
[REDACTED]. (A14073-75). Kaneka's own analysis establishes that [REDACTED]
[REDACTED]. (A6097, Table 3; A6856, Table 3).

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[REDACTED]. Accordingly, the atmosphere in the extraction tank does not meet the “inert gas atmosphere” limitation.

In opposition to Shenzhou’s motion for summary judgment, Kaneka tried to raise an issue of fact concerning the actual composition of the atmosphere in the extracting tank, but those arguments are not asserted in Kaneka’s opening brief and so are waived. (A7921-47; Kaneka’s Br., generally). For that reason, Shenzhou will only note that Kaneka’s various arguments below—some of which distort and misrepresent Shenzhou’s extracting process—are all belied by [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED].

Extracting in a “sealed tank”: The District Court found that Shenzhou does not meet the extracting in a sealed tank limitation of claims 22 and 33 because Shenzhou’s [REDACTED]. (A14075-76). Kaneka’s own expert observed [REDACTED]. (A6067-69). [REDACTED]

[REDACTED]

[REDACTED]. (A5755-56, 6023-6024, 6067-69).

Accordingly, the extraction tank is not sealed, and the condenser is not part of the “tank” used for extracting.

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Oxidizing step in claimed order: The District Court found that Shenzhou did not meet any of the ordered oxidizing steps of any of the claims because [REDACTED].

(A14076-78). The claims require on their face that oxidizing be done either before extracting or after extracting; oxidizing during extracting is precluded. Again, Kaneka's own analysis establishes that [REDACTED].

[REDACTED].

[REDACTED].

[REDACTED].

[REDACTED].

[REDACTED].

[REDACTED]. (A6097, Table 3; A6856, Table 3).

2. Even the Texas Court's Alternative Constructions Support the District Court's Summary Judgment of Non-Infringement

Though it is questionable whether Kaneka is entitled to seek a construction other than what it proposed below, Kaneka suggests that this Court adopt the Texas Court's claim constructions. But Kaneka fails to explain how the Texas Court's

¹⁷ The evidence at the ITC indicated [REDACTED].

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constructions (or non-constructions) of any of the disputed terms would affect the District Court's summary judgment of non-infringement. As already noted above, Kaneka has waived the point by not explaining it. Accordingly, even if this Court adopts the Texas Court's constructions, the District Court's summary judgment of non-infringement can be affirmed on the basis of that waiver.

But even if the Court entertains Kaneka's argument, as explained throughout, Shenzhou's non-infringement position does not turn on the exact words of the constructions, and even under the Texas Court's constructions, the District Court's summary judgment of non-infringement should be affirmed.

The Texas Court construed "inert gas atmosphere" to mean "an atmosphere substantially free of reactive gases." (A3332-3337). [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] does not meet the "inert gas atmosphere" limitation as construed by the Texas Court. (A5221-22; A5972-6036; A6097, Table 3; A6856, Table 3). Ambient air includes oxygen, a reactive gas, [REDACTED]

[REDACTED].

The Texas Court construed "sealed tank" to require "preventing exposure of its contents to the atmosphere." (A3338-3342). Since Shenzhou [REDACTED]

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[REDACTED],
Shenzhou's process fails to "prevent[] exposure of its contents to the atmosphere."

This is confirmed by Kaneka's observation of [REDACTED]
[REDACTED]
[REDACTED]. (A6097, Table 3; A6856, Table 3).

The Texas Court refused to construe the oxidizing steps. (A3351). That cannot help Kaneka's opposition to Shenzhou's motion for summary judgment of non-infringement, and Kaneka again fails to offer any explanation. On their face the claims limit the order of the oxidizing and extracting steps, precluding oxidizing during extraction, and requiring substantially complete oxidation at the oxidation step. Since the undisputed evidence shows [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]. Accordingly, no construction is necessary to affirm the District Court's summary judgment of non-infringement.

VI. CONCLUSION AND STATEMENT OF RELIEF SOUGHT

The District Court's summary judgment of non-infringement should be affirmed. Kaneka waived the challenge to the summary judgment ruling by not addressing the point in its opening brief. But even on the merits, the District

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Court's claim constructions are correct, and undisputed evidence shows that Shenzhou's process does not infringe.

The exact wording of the claim constructions is not critical to affirming the summary judgment of non-infringement. If an "inert gas atmosphere" is construed to preclude an atmosphere that oxidizes reduced CoQ₁₀, then independent claims 1 and 11 and their dependent claims are not infringed because [REDACTED]

[REDACTED]. If a "sealed tank" is sealed and a tank, then independent claims 22 and 33 and their dependent claims are not infringed because [REDACTED]

[REDACTED]. If the oxidizing step must be done before or after, but not during, the extracting step, none of the claims are infringed because [REDACTED]. If the oxidizing

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**REDACTED: CONTAINS MATERIAL
SUBJECT TO PROTECTIVE ORDER**

step requires substantially complete oxidation in the recited order, none of the claims are infringed because [REDACTED]

[REDACTED].

Respectfully Submitted,

K&L GATES LLP

Dated: August 5, 2014

By: /s/ Timothy P. Walker

Timothy P. Walker
timothy.walker@klgates.com
L. Howard Chen
howard.chen@klgates.com
Harold H. Davis, Jr.
harold.davis@klgates.com
Jas Dhillon
jas.dhillon@klgates.com
Matthew B. O'Hanlon
matthew.ohanlon@klgates.com

Attorneys for Defendant-Appellee
Shenzhou Biology and Technology
Co., Ltd.

PROOF OF SERVICE

I certify that a true and correct copy of the foregoing **APPELLEE**
SHENZHOU BIOLOGY AND TECHNOLOGY CO., LTD.'S PRINCIPAL
BRIEF [NON-CONFIDENTIAL VERSION] was served by ECF system on
counsel of record for the parties.

In addition, I served the above-referenced document on the Clerk of the
Court and the interested parties in this action by placing true copies thereof
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CARTER LEDYARD & MILBURN, LLP
Keith D. Nowak, Esq.
nowak@clm.com
2 Wall Street
New York, NY 10005
Tel: (212) 732-3200
Fax: (212) 732-3232
[TWO COPIES]
[VIA FEDEX AND E-MAIL]

RALEY & BOWICK, LLP
Robert M. Bowick Jr.
rbowick@raleymbowick.com
1800 Augusta Drive, Ste 300
Houston, Texas 77057
Tel: (713) 429-8050
Fax: (713) 429-8045
[TWO COPIES]
[VIA FEDEX AND E-MAIL]

Counsel for Kaneka Corporation

MEI & MARK LLP
Lei Mei
mei@meimark.com
Xiang Long
xlong@meimark.com
Reece Nienstadt
rnienstadt@meimark.com
P.O. Box 65981
Washington, DC 20035
Telephone: 888-860-5678
Facsimile: 888-706-1173
[TWO COPIES]
[VIA FEDEX AND E-MAIL]

*Counsel for Xiamen
Kingdomway Group Company
and Pacific Rainbow
International Inc.*



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I declare under penalty of perjury that the foregoing is true and correct.

Executed on: August 6, 2014

By: /s/ Timothy P. Walker

Timothy P. Walker

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief contains 13,768 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). The brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman size 14.

Dated: August 6, 2014

By: /s/ Timothy P. Walker
Timothy P. Walker